IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	:	1616
Examiner	:	Frank Choi
Applicant(s)	:	Todd P. Foster, William M. Moseley, Satish K. Singh
Serial Number	:	09/500246
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For	:	PHARMACEUTICAL IMPLANT CONTAINING IMMEDIATE RELEASE AND SUSTAINED RELEASE COMPONENTS AND METHOD OF ADMINISTRATION

Commissioner of Patents and Trademarks
Washington, DC 20231

#18
5-18-01

RESPONSE

Sir:

In response to the Office Action dated November 21, 2000 (Paper No. 5), reconsideration is requested in light of the following remarks.

Claims 1, 4-15 and 17-25 are pending in the present application.

Claims 1, 4-15 and 17-25 have been rejected as being unpatentable under 35 U.S.C. §103 over US 5,288,496 in view of US 5,654,496 and US 4,652,411. This rejection is respectfully traversed.

Applicants respectfully note the Examiner's comments in the Official Action of November 21, 2000. As has been set out in judicial precedent from the United States Court of Appeals for the Federal Circuit, in order for the Examiner to sustain the burden of a prima facie rejection it must be demonstrated that: (1) the prior art relied upon, coupled with the knowledge generally available in the art at the time of invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify or combine references; (2) the proposed modification must have had a reasonable expectation of success at the time the invention was made; and (3) the prior art combination of references must teach or suggest all the limitations of the claims. All of the teachings, suggestions and expectation of success must come from the prior art, and not Applicants' disclosure.

Moreoever, Applicants further disagree that they have failed to point out the patentable novelty as distinguished from the prior art cited of record. With respect to independent claims 1 and 13, and those dependent therefrom, Applicants have limited their claims to embodiments where the first delivery vehicle is selected from the group consisting of encapsulants where the coating wall material is highly soluble in body fluids, porous or freeze-dried solid compositions, solid tablets or pellets containing a disintegrating agent which causes the solid tablet or pellet to rapidly break down when in body fluids, solid tablets or pellets containing said biologically active material in fine or micronized particle sizes, an osmotic delivery system where the osmotic system is such that a substantial amount of the active is released upon implantation and mixtures thereof; and wherein the second delivery vehicle is selected from the group consisting of encapsulated solutions or suspensions, biodegradable solid substances, conventional tablet/pellet ingredients, conventional tablet/pellet ingredients coated with a polymeric membrane to control release, conventional tablets or pellets containing said biologically active material having large particle sizes, matrix-tablets based on gel-forming excipients, matrix-type systems based on non-biodegradable polymers, membrane-type systems based on non-biodegradable polymers , matrix-type systems based on biodegradable polymers, matrix–type systems implant based on lipidic excipients, mass transfer systems based on osmotic pressure pumping through a hole in an impermeable coating and mixtures thereof. As these delivery vehicles are nowhere suggested nor disclosed in the prior art references, the references cannot be properly applied as against the instant claims.

More specifically, both the primary and first cited secondary reference disclose the use of specially designed microparticles to obtain the delivery vehicles of their invention. The microparticles have to be made from known biodegradable synthetic polymers, casein, albumin, and waxes. The process involves solubilization of polymer and active in an organic solvent system, emulsification of the solution, removal of solvent by evaporation, and collection of the microparticles. Various release rates are obtained by altering the size or size distribution of the microparticles used. The dosage is injected by first suspending the particles in water or saline and then injecting at site.

By direct comparison, the use of microparticles as delivery vehicles do not comprise any aspect of the claimed invention.

Moreover, referring to Lewis at Col. 3, lines 12-15, the concept of multiphasic release is explained as describing a product having a faster release of active to an animal based upon the growth of the animal. Accordingly, what is desired is that a predetermined amount of active be administered based upon the size of the animal (i.e., more drug is delivered as the animal gets larger). By comparison, in the instant invention, the differential release is directed to both immediate release of active (to provide an instanteously pharmacological effect) and sustained release of active (to provide a sustained pharmacological effect).

The second cited secondary reference (Okada et al.) only discloses the desirability of developing a sustained release pharmaceutical composition. However, the Okada et al. reference nowhere discloses nor contemplates differential release of the same pharmaceutically active agent via the use of discrete delivery vehicles. In direct comparison, applicants' claimed invention is specifically directed to differential release of the same pharmaceutically active agent via the use of discrete delivery vehicles. As such, Okada et al. cannot be used to negative patentability of the claimed invention.

Applicants note the Examiner's suggestion at Page 3 of the Office Action that the limitations made by the amendment cannot be interpreted as necessarily excluding microparticles. Applicants strenuously disagree. They are clearly allowed to exclude from a claim, knowledge which was clearly within the skill of the artisan at the time of filing. Applicants do not disagree that the use of microparticles as specifically disclosed in the cited references constitutes prior art. However, applicants' claimed invention does not include such embodiments. If deemed necessary to solicit allowance, Applicants are willing to include a negative proviso into the claims that the delivery vehicle not include microparticles.

In addition to the arguments as presented above, applicants respectfully submit that independent claim 11, and dependent claim 12 are additionally patentable as none of the cited references disclose or suggest the use of one or more pellets or tablets containing a disintegrating agent with one or more pellets or tablets not containing a disintegrating tablet to administer melengestrol acetate to a host.

Accordingly, it is respectfully submitted that the rejection of claims 1, 4-15 and 17-25 as being unpatentable under 35 U.S.C. §103 over US 5,288,496 in view of US 5,654,496 and US 4,652,411 must be withdrawn as a matter of law.

Claims 1, 4-7, 10, 13-15, 17, 19 and 21-25 have been rejected as being unpatentable under 35 U.S.C. §103 over Stevens et al. This rejection is respectfully traversed.

Stevens et al. fails to disclose or suggest the very crux of the claimed invention, namely, differential release of the same active ingredient. The differential release allows for immediate treatment of a condition (which may be required for some conditions) followed by a longer acting regimen primarily used to counteract the condition once the immediate treatment has brought such condition under control. Stevens et al. fails to remotely consider such a possibility.

Moreover, the primary purpose of the delivery of the antibiotic according to Stevens is to prevent infection at the treatment site. It in no way functions to treat the underlying medical condition. By stark comparison, Applicants' claimed invention is wholly directed to the treatment of the underlying condition via differential release of the same biologically active composition.

Accordingly, the rejection of Claims 1, 4-7, 10, 13-15, 17, 19 and 21-25 as being unpatentable under 35 U.S.C. §103 over Stevens et al. must be withdrawn as a matter of law.

Claims 1, 6-10, 13, and 17-25 have been rejected as being unpatentable under 35 U.S.C. §103 over Rickey et al. This rejection is respectfully traversed.

Rickey et al. fails to disclose or suggest the very crux of the claimed invention, namely, differential release of the same active ingredient. The differential release allows for immediate treatment of a condition (which may be required for some conditions) followed by a longer acting regimen primarily used to counteract the condition once the immediate treatment has brought such condition under control. Rickey et al. fails to remotely consider such a possibility.

Moreover, Rickey et al. relies upon microparticle technology which forms no part of the instant invention. See the above discussion, supra.

Accordingly, the rejection of Claims 1, 6-10, 13, and 17-25 as being unpatentable under 35 U.S.C. §103 over Rickey et al. must be withdrawn as a matter of law.

Claims 1, 4-7, 10, 13-18 and 21-25 have been rejected as being unpatentable under 35 U.S.C. §103 over Guittard et al. This rejection is respectfully traversed.

Guittard et al. fails to disclose or suggest the very crux of the claimed invention, namely, differential release of the same active ingredient. The differential release allows for immediate treatment of a condition (which may be required for some conditions) followed by a longer acting regimen primarily used to counteract the condition once the immediate treatment has brought such condition under control. Guittard et al. fails to remotely consider such a possibility.

Accordingly, the rejection of Claims 1, 4-7, 10, 13-18 and 21-25 as being unpatentable under 35 U.S.C. §103 over Guittard et al. must be withdrawn as a matter of law.

If there are any questions regarding this Response, the Examiner is cordially invited to contact the undersigned attorney at (616) 833-1861. A Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date: 8 May 2001

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